

APPROVED

**UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
LIVESTOCK AND SEED PROGRAM**

Preparing Activity:
USDA, AMS, LS, STDZ--Rm. 2603-S
April 30, 2003

**TECHNICAL REQUIREMENTS SCHEDULE-GB-2003
FOR USDA PURCHASES OF GROUND BEEF ITEMS, FROZEN**

I. SCOPE

This Technical Requirements Schedule (TRS)-GB-2003 is for use by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock and Seed Program (LS) for its program to procure fresh ground beef products, frozen.

II. APPLICABLE DOCUMENTS

The following documents are incorporated as part of this USDA, TRS-GB-2003:

- Meat Grading and Certification (MGC) Branch Instruction Manual.
- Audit Review and Compliance (ARC) Branch Procedures, Series 1000.

III. CHECKLIST OF REQUIREMENTS

A. ITEMS

The contractor's technical proposal will declare which items will be offered to USDA. BULK or PATTIES to be specified within USDA procurement documents.

- | | |
|--|--------------|
| 1. BULK: | Product Code |
| Ground Beef (10-pound bulk packaged) | A608 |
| Ground Beef, 1-pound packages | A609 |
| Coarse Ground Beef to be Further Processed into Cooked Items | A594 |
| 2. PATTIES: | |
| Ground Beef Patties | A626 |
| Ground Beef and Vegetable Protein Product Patties | A616 |
| Ground Beef Patties, Not to exceed (NTE) 10% Fat | A627 |

B. MATERIAL

The contractor's technical proposal and process must assure that products comply with the following material requirements.

1. Domestic Origin - Beef must originate from U.S. produced livestock and will be verified in accordance with ARC Instruction 1010 for Domestic Product Suppliers and Material Requirements Verification.
2. Slaughter Requirements - Beef must originate from slaughter establishments that will comply with the following requirements:
 - a) Non-ambulatory cattle - Have a segregation plan that assures non-ambulatory cattle (cattle that are unable to walk under their own power, commonly known as "downers") are handled in accordance with Food Safety Inspection Service (FSIS) Directive 6900.1R1 - Humane Handling of Disabled Livestock, issued 11/02/98. If "downers" are slaughtered, carcasses originating from such animals must be **segregated** and the product from them cannot be included in USDA purchased ground beef.

- b) Stunning Process - An air-injected pneumatic stunner shall not be used.
 - (1) Pathogen Intervention Steps - Include at least two pathogen intervention steps. One of the intervention steps shall be steam pasteurization, an organic acid rinse, or a 180°F hot water wash and must be a critical control point (CCP) in their FSIS recognized slaughter process Hazard Analysis Critical Control Point (HACCP) plan.
 - c) Carcass Testing - Routinely test carcasses for *E. coli* O157:H7 to verify effectiveness of interventions at CCP, as provided in Section VI. B. 3 of FSIS Directive 10,010.1 dated 2-1-98.
 - d) Spinal Cord Removal - Remove all spinal cord tissue during the slaughter process.
3. Boneless Beef Requirements
- a) Quality Control Program - The boneless beef supplier's quality control program must be documented in the contractor's technical proposal and have received a satisfactory onsite capability assessment by the ARC branch.
 - b) Lot – For the purpose of this section, a lot shall consist of all boneless beef produced between clean-ups and that is from a single slaughterer or from a single processor.
 - c) Traceability - Contractors are responsible for providing traceability of boneless beef that is derived from approved sources that comply with the above domestic origin and slaughterer requirements. They must have documentation and a program in place that verifies the source of raw materials used in each lot of product.
 - d) Handling - All boneless beef must be maintained in excellent condition. The contractor's technical proposal shall include detailed production scheduling that addresses time and temperature controls necessary to maintain excellent condition of the boneless beef and to meet the following applicable requirements. Frozen boneless beef may be used provided it is ground into the final product within 60 days from the date of pack.
 - e) Objectionable Materials - The processor must assure the removal of major lymph glands (prefemoral, popliteal, and prescapular), bone, cartilage, and the following heavy connective tissues:
 - (1) White fibrous – Shoulder tendon, elbow tendon, silver skin, sacrociatic ligament, opaque periosteum, serous membrane (peritoneum), tendinous ends of shanks.
 - (2) Yellow elastin – Back strap and abdominal tunic.

- f) Microbial Testing - All lots of fresh chilled boneless beef to be ground for USDA must be tested for all microbes listed in Table 1.

Table 1			
AMS MICROBIAL REQUIREMENTS FOR BONELESS BEEF			
Microbial Test	Upper Specification Limits	Critical Limits	CI or C_{pu} Value (see Appendix A)
Standard Plate Count	100,000/gram	500,000/gram	C_{pu} ≥ 1
Total <i>Coliforms</i>	500/gram	2,500/gram	C_{pu} ≥ 1
<i>E. coli</i>	100/gram	1,000/gram	C_{pu} ≥ 1
<i>Salmonella</i>		Positive Results/25 grams	CI ≤ 0.05
<i>E. coli</i> O157:H7		Positive Results/325 grams	CI ≤ 0.05

- (1) Sample Preparation – From each lot, a composite sample will be prepared from at least 4 randomly selected samples (of approximately equal size) of boneless beef. The samples shall be ground/chopped and blended together. From the mixture, a single sample shall be drawn and submitted for analysis to an AMS designated laboratory (quantity of the single sample will be determined by the laboratory). Alternative sample preparation procedures will be considered within the technical proposal provided that there is assurance that all specification requirements are met.
 - (2) Testing and Results - The sample will be analyzed by the AMS designated laboratory for microbial levels listed in Table 1. The microbial test for all microbes, except for *E. coli* O157:H7, will be in accordance with the applicable test methods listed in the Compendium of Methods for the Microbiological Examination of Foods (current edition), published by the American Public Health Association. The presence of *E. coli* O157:H7 will be determined using the referenced test method within the "USDA/FSIS Microbiology Laboratory Guidebook, 3rd Edition/1998, Chapter 5" for *E. coli* O157:H7 requirements. The contractor will record and plot the results on control charts and histograms for each microbial test (as illustrated in Appendix A and further defined in Appendix D). The control charts and histograms will be maintained so that capability may be determined according to the requirements within Appendix B.
 - (3) Requirements – The capability of a boneless beef supplier to comply with microbial requirements will be based on assessment of control charts and histograms. Test results will be monitored by the contractor and AMS to determine capability of the boneless beef supplier's process according to Appendix B. Ineligible boneless beef suppliers may petition AMS to reenter the program provided corrective actions have been implemented, proven effective, and a satisfactory onsite assessment audit by AMS has been received.
4. Ground Beef Requirements
- a) Lot - For the purpose of this section, a lot is defined as the amount of finished ground beef produced between "clean ups".
 - b) Traceability - Each lot of boneless beef to be ground for USDA must be traceable to the boneless beef microbial test results.

- c) Microbial Testing – All lots of ground beef will be tested for all microbes listed in Appendix C.
- (1) Sample Preparation - A composite sample from the lot will be prepared from at least 4 randomly selected samples of finished ground beef, each consisting of 1 pound. A single one pound sample will be prepared and submitted to the AMS designated laboratory for analysis.
 - (2) Testing and Results - The sample will be analyzed for *Salmonella* and all other microbes listed in Appendix C by the AMS designated laboratory using the applicable test methods listed in the Compendium of Methods for the Microbiological Examination of Foods (current edition), published by the American Public Health Association. The results will be recorded and plotted on control charts and histograms for *Salmonella* and other microorganisms as illustrated in Appendix A. Test results will be monitored by the contractor and AMS. The control charts and histograms will be maintained so that acceptability may be determined according to the requirements within Appendix C.
 - (3) Testing for *E. coli* O157:H7 – The ground beef sample submitted to the AMS designated laboratory will also be tested for the presence of *E. coli* O157:H7 using the referenced test method within the "USDA/FSIS Microbiology Laboratory Guidebook, 3rd Edition/1998, Chapter 5" for *E. coli* O157:H7 requirements. When presence of *E. coli* O157:H7 is positive per 325 gram sample:
 - (a) FSIS will be notified for final disposition of the product.
 - (b) The contractor shall conduct a cause and effect analysis to determine the appropriate correction action necessary to eliminate the probable cause. The corrective actions must be implemented and proven effective.
 - (4) Requirements –The capability of the contractor to comply with microbial requirements will be based on assessment of control charts and histograms. Test results will be monitored by the contractor and AMS to determine acceptability of the process according to APPENDIX C. Ineligible contractors may petition AMS to reenter the program provided corrective actions have been implemented, proven effective, and a satisfactory onsite assessment audit by AMS has been received.

5. Meat Recovery Systems

- a) Mechanical Separation - Beef that is mechanically separated from bone with automatic deboning systems, advanced lean (meat) recovery (AMR) systems or powered knives, will not be allowed.
- b) Lean Finely Textured Beef - Lean beef that is processed from fat boneless beef trimmings and is finely textured is allowed provided it does not exceed 10 percent by weight of the combined finished product. The finely textured product shall be labeled "Lean Finely Textured Beef" and must be produced from boneless beef that complies with all **MATERIAL** requirements for boneless beef. The contractor shall document all procedures for handling of finely textured lean beef trimmings and must use it within 60 days of the date of production. Finely textured lean beef trimmings may not be used in USDA coarse ground beef.

6. Desinewed Beef – Must be in discernible pieces (chunks). The desinewing process must demonstrate the ability to remove heavy connective tissue in boneless beef.

7. Ground Beef Patties with Vegetable Protein Product (VPP) - The VPP will be hydrated to yield 18% protein (as is basis).
 - a) Source - The source of VPP will be soy.
 - b) Fortification - The VPP must be fortified to meet the nutritional specifications established by the USDA, Food and Nutrition Service (FNS) Regulations. To ensure compliance, the VPP used the label must state: "This product meets USDA-FNS requirements for use in meeting a portion of the meat/meat alternate requirement of the child nutrition programs."
 - c) Type, Texture, and Combination Rate - The physical characteristics of VPP, in the dry form, must be either granular or textured. The types of soy that may be used and combination rates shall be as set forth in Table 2.

Table 2

Types of Soy (% Protein "As is Basis")	Maximum Percent of Hydrated VPP in the Combined Finished Product
Textured Flour (50%)	15.0
Granular Concentrate (65%)	20.0
Flaked Textured Concentrate (65%)	25.0
Textured Isolate (85%)	25.0

NOTE: VPP (of any texture) that has been hydrated by the VPP manufacturer may be used provided that: The product is frozen and the protein content (as is basis) of the hydrated VPP is stated on the manufacturer's label.

8. Ground Beef Patties, NTE 10% Fat – The patties shall not have any non-meat ingredients added.

C. PROCESSING

The contractor's technical proposal and process shall assure compliance with the following requirements:

1. Grinding and Blending -
 - a) Ground Beef - Boneless beef shall be ground twice, with the final grind passing through a 1/8 inch grinding plate. Blending after final grinding is allowed only to the extent that it doesn't affect the appearance of the finished ground beef.
 - b) Coarse Ground Beef – Boneless beef shall pass at least once through a grinding plate that is no smaller than 3/4 inch or no larger than a 1.0 inch.
 - c) Fat Break-Outs – The grinding, blending, and packaging process shall be conducted in a manner that precludes large fat "break outs" (globes greater than 1.0 cubic inch) in the finished product.
2. Bone Collector/Extruder Systems - Except for Coarse Ground Beef, a bone collector/extruder system must be in operation to remove bone, cartilage, and heavy connective tissue during the final grind of all products. For those collector/extruder systems that have a secondary lean recovery system, the product from the secondary recovery system shall be allowed provided it does not exceed more than 2.0 percent of finished product weight (on a lot weight basis).
3. Scoring or Waffling of Patties - Raw ground beef patties must be round and scored or waffled on both sides.

4. Metal Detection – All product shall be free of metal contaminates. Detection of stainless steel, ferrous, and non-ferrous (e.g., lead, copper, and aluminum) metals is required. The contractor's technical proposal must identify and describe the equipment, detection procedure, sensitivity levels, frequency of validating the equipment, location, and corrective action procedures.

D. STATE OF REFRIGERATION

1. Bulk Packaged Ground Beef Items – Shall be frozen to 0°F within 72 hours after completion of the final grinding of the involved lot.
2. Patties - will be individually quick frozen (IQF) to 10°F or below prior to packaging and then frozen to 0°F or lower within 24 hours after completion of packaging and packing of the lot.
3. Shipping – All USDA ground beef products will not exceed 0°F at the time of shipment or delivery.

E. FAT LIMITATIONS

The contractors will establish a target average of 15 percent fat for all ground beef products except for the ground beef patties NTE 10 percent fat. The upper and lower specifications limits will be 18 and 12 percent fat respectively. The target fat content will be declared on the shipping container label and the nutrition facts panel. For ground beef patties NTE 10 percent fat, the upper specification limit will be 10 percent. The contractor shall declare lot size and maintain statistical process control procedures for fat content that are monitored by FSIS and made available for process capability assessment by AMS. The contractor shall declare the laboratory, test method and Statistical Process Control (SPC) charting method within their technical proposal.

1. Sampling and Testing
 - a) Sampling and testing - The contractor will select 4 individual sample units (selected after initial grinding or blending) to be analyzed for fat content from each production lot destined for USDA. The sample unit size will be determined by the testing method used by the contractor's laboratory.
 - b) Recording results – The contractor will record and plot the results on variable data control charts and histograms. Control charts must have statistically derived upper and lower control limits (+/- 3 standard deviations from the mean). Control charts will be used to determine if the process is in statistical control. Histograms will be used to determine process capability. No product shall be allowed delivery to USDA with average test results that are outside the upper and lower specification limits.
 - c) Process Capability Assessment – Twenty (20) consecutive production lot results (that include the last production lot) will be plotted on histograms for capability assessment. The processor's capability (C_{pk}/C_{pu}) shall be 1 or higher.
 - d) The contractor and AMS will evaluate control charts and histograms with consecutive results (not to exceed 20) that include the last production lot.

2. AMS Assessment – On a weekly basis, the AMS agent will randomly select independent samples (each consisting of four sample units) from two production lots that are sent to the AMS laboratory for fat analysis. After a minimum of 20 consecutive AMS results are received, AMS will plot the results on histograms for comparison and to conduct a process capability assessment. AMS reserves the right to deem a supplier as unreliable for considering future contract awards when:
 - a) AMS calculated process average varies more than 1 percent from the contractor's calculated process average results,
 - b) AMS calculated process capability (C_{pk}/C_{pu}) is less than 1 for results within the upper and lower specification limits, or
 - c) The contractor's calculated process capability (C_{pk}/C_{pu}) is less than 1 for results within the upper and lower specification limits.

F. PATTY WEIGHT, THICKNESS, AND SHAPE

The contractor's technical proposal and process will assure that the following requirements are met:

1. Patty weight – Target weight will be 3.0 ounces. Acceptable weight tolerance range will be 2.9 to 3.1 ounces.
2. Patty thickness – 5/16 inch (+/- 1/16).
3. Shape - Patties shall be round in shape and waffled or scored on both sides.

G. PREPARATION FOR DELIVERY

The contractor's technical proposal and process will assure that all packaging, packing, closure, marking and palletization comply with the National Motor Freight Regulations and FSIS regulations and the requirements listed below. The contractor also must have procedures for verifying the net weight of shipping containers.

1. Packaging and Packing
 - a) Fine Ground Beef (Product Code A608) – Fine ground beef must be vacuum packaged or packaged in casings and sealed. All packages shall be tamper proof. Each package will weigh 10 pounds. The casings or packages shall be closed by metal clips or by a heat-sealing method. Four (4) packages will be placed into each shipping container.
 - b) Fine Ground Beef (Product Code A609) – Fine ground beef must be vacuum packaged or packaged in casings and sealed. All packages shall be tamper proof. Each package will weigh 1 pound. Forty (40) packages will be placed into each shipping container.
 - c) Coarse Ground Beef (Product Code A594) - Coarse ground beef must be bulk packaged (with no packaging materials) directly into leak-proof shipping containers with fiberboard that is wax impregnated, has a moisture barrier coating, or have plastic laminated interior panels.
 - d) Ground Beef Patties (Product Codes A616, A626, and A627) - Patties must be packaged into flexible (plastic) primary containers and sealed or vacuum packaged in tamper proof containers. Placement of sealed plastic containers within fiberboard primary containers (boxes) is optional. Separation material between patties is not required provided the IQF patties do not stick together at the time of shipment.

- (1) Flexible Containers - Either four 10-pound or eight 5-pound flexible containers will be placed into each shipping container. Flexible containers shall be mechanically sealed (hand twisting or hand tying is not acceptable).
 - (2) Fiberboard Containers – When fiberboard primary containers are used, at the option of the contractor, either four 10-pound or two 20-pound fiberboard containers will be placed into each shipping container.
- e) Style and Size of Shipping Containers - Only one style and size of primary and shipping container may be used in any one delivery unit.
- 2. Net Weight
 - a) Fine Ground - will be 40 pounds per shipping container.
 - b) Coarse ground beef - will be packed in leakproof shipping containers to a net weight of 60 pounds.
- 3. Closure

Shipping containers will be closed by strapping, taping or gluing. When strapping is used, the initial closure (usually the bottom of container) shall be secured by the gluing or taping method.
- 4. Marking of Containers

Both primary and shipping containers will be labeled to include all information required by FSIS regulations and shall have a printed code that is traceable to the production lot and date.

 - a) Ground Beef, 1-pound package labels will have the following information included on commercially labeled packages:
 - (1) Safe handling instructions.
 - (2) Nutrition Facts panel (to include fat declaration of 15 grams of fat per 100 gram serving).
 - (3) The “best if used by” date (180 calendar days from the date of production).
 - (4) The FSIS establishment number.
 - (5) A code number that will indicate traceability to production lot and date.
 - b) Shipping Containers - Commercially marked shipping containers will include the information as follows:
 - (1) USDA Shield (at least 2 inches high and appearing on the top of the container or on the principle display panel).



- (2) Contract Number.
 - (3) The product name shall include no additional disclaimers and qualifiers to the name and code listed in Table 3 below.
 - (4) fat declaration.

Table 3 - Shipping Container Marking Requirements

Product Name that shall appear on the label.	Product Code
Ground Beef <u>1/</u>	A608
Ground Beef, 1- Pound Packages <u>2/</u>	A609
Coarse Ground Beef to be Further Processed into Cooked Items	A594
Ground Beef Patties <u>1/</u>	A626
Ground Beef and VPP Patties <u>1/ 3/</u>	A616
Ground Beef Patties NTE 10 percent fat <u>1/</u>	A627

1/ Shall include the statement "For Institutional Use Only" on the principle display panel.

2/ UPC Shipping Container Code Required.

3/ The ingredient statement must include the identification of added ingredients and nutrients.

All labeling shall be illustrated in the offeror's technical proposal.

(5) Bar Code - For shipping containers with Ground Beef, 1- Pound Packages, a Universal Product Code (U.P.C.) code and symbol will be required. A code, called Interleaved 2 of 5 (I 2/5) bar code, will appear on each shipping container in accordance with the U.P.C. guidelines published by the Uniform Code Council (UCC). A 14 digit I 2/5 bar code, which consists of the number 10715001016093, must appear on the lower corner of one side panel of each shipping container. The U.P.C. guidelines describe the requirements for the proper placement, printing, readability, and scanability for the bar coding. The complete code must be printed in machine and human readable form. The start and stop indicators must be included in the bar code symbols. Package manufacturers, printers, and film master suppliers are familiar with this symbology. Further information may be obtained from the Uniform Code Council, Inc.; 8163 Old Yankee Road, Suite J; Dayton, Ohio 45458. Telephone: (513) 435-3870. The Department of Agriculture has acquired a unique manufacturer's identification number for this application. Contractor's need not join the UCC.

5. Palletized Unit Loads – All product shall be stacked on new or good conditioned pallets and palletized with shrink wrap plastic.
6. Total net weights per delivery unit - The delivery units for each of the respective product codes are as follows:

Product Code	Pounds Per Delivery Unit
A608, A609, A579	40,000
A626, A616, A627, A578	38,000
A594	42,000

Note: No tolerances will be allowed.

H. USDA QUALITY ASSURANCE

1. WARRANTY AND COMPLAINT RESOLUTION

A warranty and customer service clause that includes customer complaint resolution procedures shall be included in the technical proposal. These procedures will be used to resolve product complaints from recipient agencies or AMS.

2. AMS MONITORING AND PRODUCTION ASSESSMENT

A MGC Branch agent must be present during the grinding process for all USDA ground beef contracts. The Agent will monitor and verify the processing steps, quality assurance activities, and corrective actions to assure that all requirements outlined in the approved technical proposal are complied with. The MGC agent will be conducting the monitoring and production verification in accordance with applicable MGC instructions. Any deviations to contractual requirements will be reported to the Contracting Officer.

3. CHECKLOADING

The contractor has the following checkloading options:

- a) Option 1 - At the request of the Contractor, AMS agents (on a fee basis) will checkload the product at the time of shipment and perform the following duties:
 - (1) Assure product temperature is at or below 0° F at the time of shipment.
 - (2) Conduct a final examination of condition of shipping containers that will be limited to visual scanning (without destructive sampling) the delivery unit for defects which may have occurred during handling and storage (e.g., crushed, torn, dirty, stained, etc.). All defective containers are unacceptable and must be corrected, removed or replaced, as applicable.
 - (3) Supervise the loading and sealing of each truck.
 - (4) Issue a final Acceptance Certificate, thereby allowing the Contractor to immediately submit invoice for payment to USDA. The AMS agent shall set forth on the original certificate the following:
 - (a) Contract number
 - (b) Notice-to-Deliver number
 - (c) Destination
 - (d) Name of product
 - (e) Product Code
 - (f) Production lot number(s) and the date each lot was produced along with the shipping container and primary container code(s) and the code used that provides traceability to production lot and date.
 - (g) Count of shipping containers and total net weight in each production lot.
 - (h) Total net weights per delivery unit
 - (i) Identity of conveyance (numbers and letters, seals, license, etc.) as applicable
- b) Option 2 - If the Contractor chooses to not have an AMS agent perform checkloading at the time of shipment, invoices for payment must be supported by:
 - (1) a recipient's signature on the bill of lading;
 - (2) a consignee's receipt evidencing date shipped and received; or
 - (3) other commercial receipt evidencing delivery of the product.

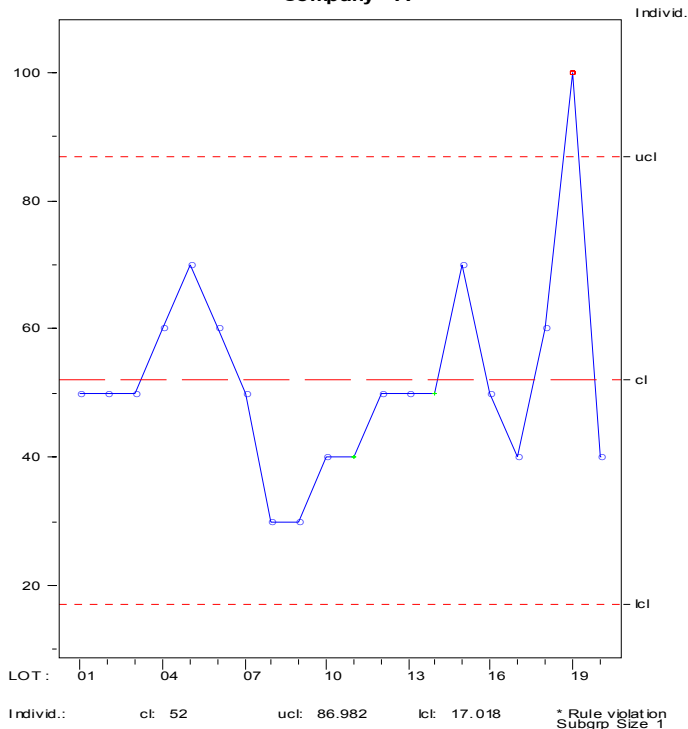
In all cases the information contained in the issuance of the final certificate "a through i" in the option 1 section and a statement that: "Product conforms with the TRS-GB-2003" must be included.

APPENDIX A

Example Statistical Process Control Charts and Histograms

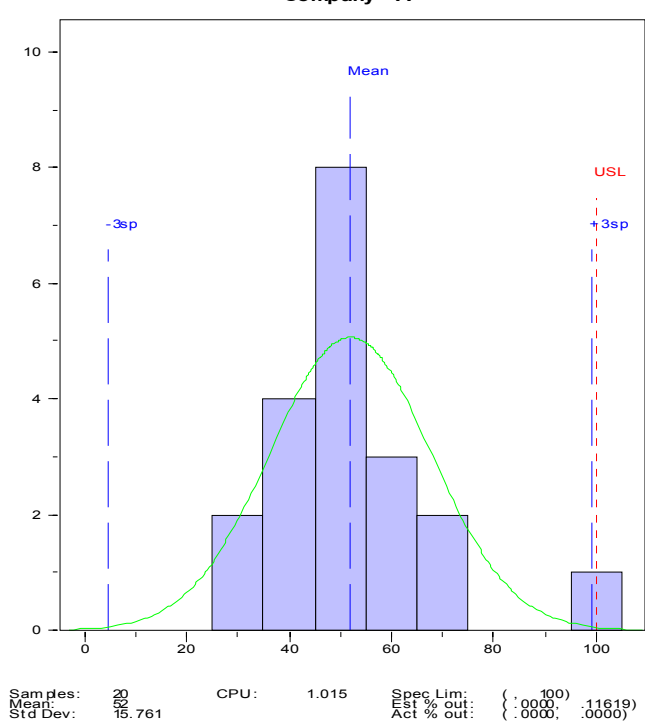
Control Chart

AMS Microbial Data
Generic E. coli
Company = A



Histogram

AMS Microbial Data
Generic E. coli
Company = A



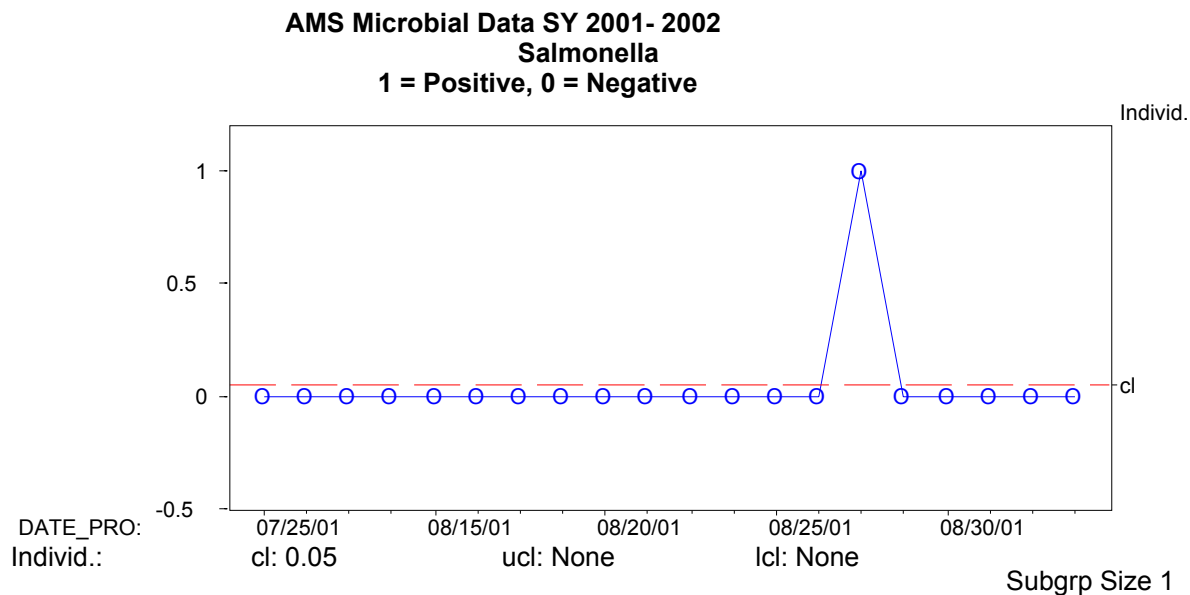
The above control chart and histogram are examples for illustrative purposes.

The control chart will have statistically derived upper control limits (ucl) and lower control limits (lcl) (+/- 3 times the standard deviation of the process average), and the central line (cl) value (process average, mean or x-bar). Since the subgroup size for microbial test is one(1), the calculation for standard deviation will be on individual measures.

The process capability value (C_{pk} or C_{pu}), is below the histogram chart (capability report). Since there are no lower specification limits within USDA microbial requirements and fat requirements for ground beef patties NTE 10% fat, the C_{pu} will be used. The C_{pk} will be used for fat requirements that have a lower and upper specification limit. The applicable upper specification limits (USL) along with the capability limits (+/- 3 times the standard deviation of the individual measures (+/- 3sp)) will be displayed within the histogram. USL for microbial requirements will be found in Table 1. The calculation for the C_{pu}/C_{pk} for microbial and fat requirements involves two steps:

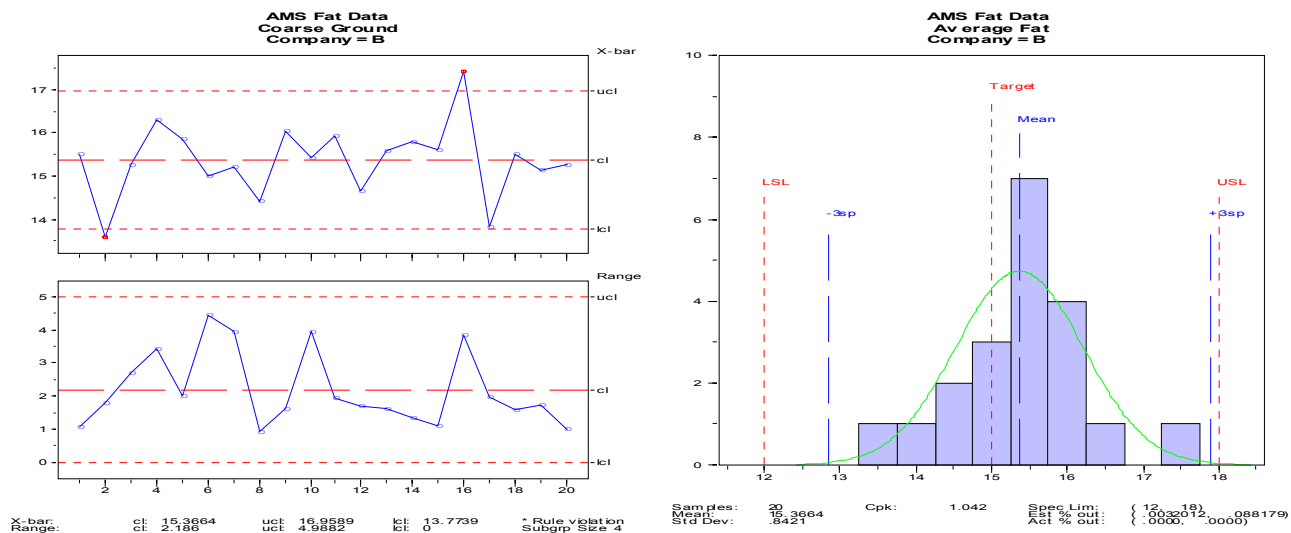
Calculation of C_{pu} with an upper specification limit only	
Step 1. The first calculation will determine the z value:	Step 2. The Z value divided by 3 will calculate the process capability (C_{pu}).
$Z \text{ value (upper)} = \frac{USL - \text{Process Average}}{\text{Standard Deviation of individual measures}}$	$C_{pu} = \frac{Z \text{ value (upper)}}{3}$
Calculation of C_{pk}	
Step 1. The first calculation will determine the min z value:	
$Z \text{ value (upper)} = \frac{USL - \text{Process Average}}{\text{Standard Deviation}}$	$Z \text{ value (lower)} = \frac{\text{Process Average} - LSL}{\text{Standard Deviation}}$
Step 2. The lower Z value divided by 3 will calculate the process capability (C_{pk}).	$C_{pk} = \frac{Z \text{ value (min)}}{3}$

Control Chart



The central line (cl) in the above control chart indicates the incidence of positive *Salmonella* results (5.0%). The results are plotted with the positive results for *Salmonella* as 1 and negative results as 0.

The charts below are illustrative of the x-bar and range control chart and the histogram that shall be used for analysis of fat test results.



APPENDIX B

AMS BONELESS BEEF PROCESS REQUIREMENTS FLOW CHART

Quality Control Program – Prior to supplying boneless beef destined for USDA, the documented quality control program as described within the technical proposal must be approved by AMS. AMS will audit the program.

Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots. Boneless meat may be ground for delivery to USDA while in process assessment status. Production lots of boneless beef will be allowed to be processed into ground beef destined for USDA except when results for *Salmonella* and *E. coli* O157:H7 are positive.

Process Capable – Results of twenty (20) consecutive lots (which will include the last recorded result) will be used to determine the process capability value (C_{pu}) and central limit value (cl). Test results will be plotted on control charts and histograms (See APPENDIX A). A process is not capable when:

- The CI and C_{pu} values do not meet the levels specified in Table 1;
- Two (2) or more results exceed the critical limits in Table 1; or
- The C_{pu} value after 2 or more results is negative.

Conditional Status – Boneless beef production lots with test results that exceed any Critical Limits listed in Table 1 may not be used in ground beef that is delivered to USDA. To regain process assessment status, the boneless beef supplier and/or the contractor must have 20 consecutive results that meet the C_{pu} and cl levels within 30 production days.

Process Capable While in Conditional Status – The supplier will be deemed ineligible when the process is not capable.

Ineligible Supplier/Contractor – An Ineligible Boneless Beef Supplier will not be allowed to supply boneless beef to any USDA contracted grinding facilities until corrective actions have been implemented, proven effective, and a satisfactory AMS assessment audit has been completed.

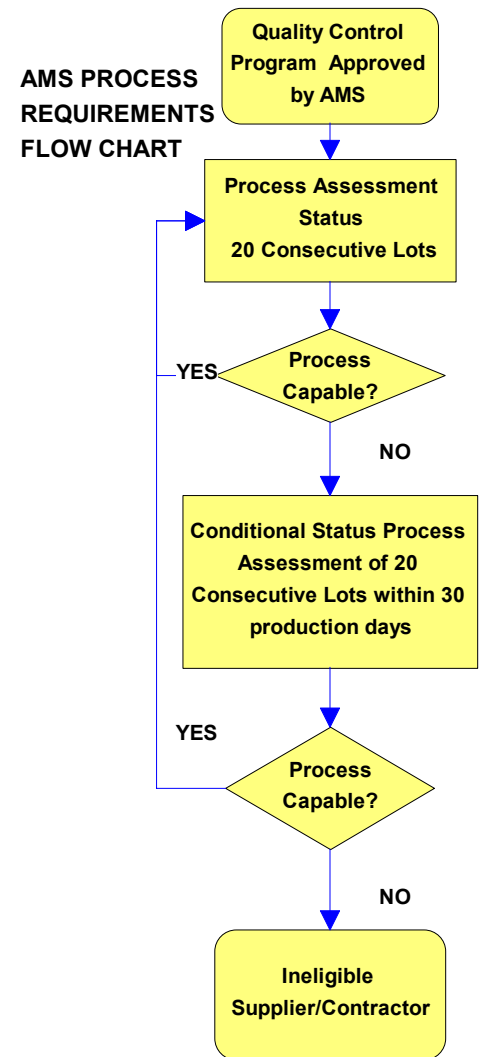


Table 1

AMS MICROBIAL REQUIREMENTS FOR BONELESS BEEF

Microbial Test	Upper Specification Limits	Critical Limits	CI or C_{pu} Value
Standard Plate Count	100,000/gram	500,000/gram	$C_{pu} \geq 1$
Total <i>Coliforms</i>	500/gram	2,500/gram	$C_{pu} \geq 1$
<i>E.coli</i>	100/gram	1,000/gram	$C_{pu} \geq 1$
<i>Salmonella</i>		Positive Results/25 grams	$CI \leq 0.05$
<i>E. coli</i> O157:H7		Positive Results/325 grams	$CI \leq 0.05$

APPENDIX C

AMS GROUND BEEF PROCESS REQUIREMENTS FLOW CHART

Quality Control Program – Prior to bidding on ground beef contracts with the USDA, the documented quality control program as described within the technical proposal must be approved. AMS will audit and monitor the program.

Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots for Standard Plate Count, Total *Coliforms*, *E.coli*, *Salmonella* and *E. coli* O157:H7. Boneless meat may be ground for delivery to USDA while in process assessment status. Production lots of ground beef will not be allowed delivery to USDA when results for *Salmonella* or *E. coli* O157:H7 are positive or the critical limits are exceeded for Standard Plate Count, Total *Coliforms*, Coagulase Positive *Staphylococci*, or *E.coli*.

Process Capable – Results of twenty (20) consecutive lots (which will include the last recorded result) will be used to determine the process capability value (C_{pu}) and central limit value (cl). Test results will be plotted on control charts and histograms (See APPENDIX A). A process is not capable when:

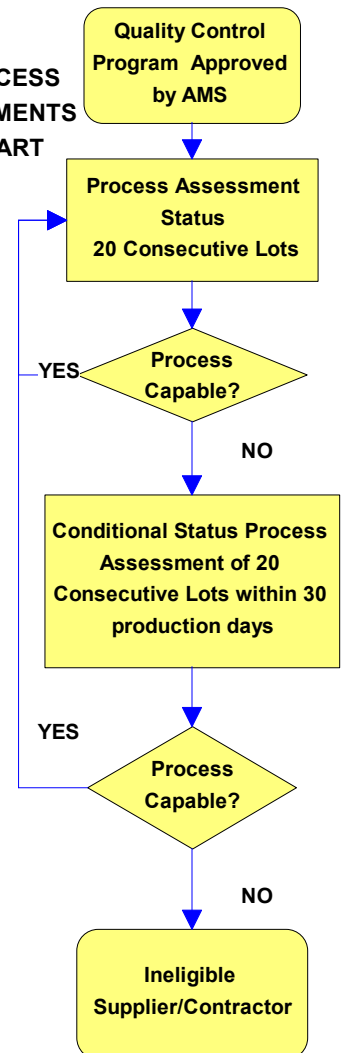
- The C_{pu} values do not meet the levels specified in the table below;
- Two (2) or more results exceed the critical limits for Standard Plate Count, Total *Coliforms*, Coagulase Positive *Staphylococci*, or *E.coli* in the table below;
- The C_{pu} value after 2 or more results is negative; or
- The Cl values do not meet the levels specified in the table below for *Salmonella* and *E. coli* O157:H7.

Conditional Status – Ground beef with test results exceeding the critical limit for Standard Plate Count, Total *Coliforms*, Coagulase Positive *Staphylococci*, or *E.coli* will not be allowed delivery to USDA. To regain process assessment status, the contractor must have 20 consecutive results that meet the C_{pu} and cl levels within 30 production days.

Process Capable While in Conditional Status – The contractor will be deemed ineligible when the process is not capable.

Ineligible Supplier/Contractor – An ineligible Ground Beef Contractor will not be allowed to supply ground beef products under USDA contracts until corrective actions have been implemented, proven effective, and a satisfactory AMS assessment audit has been completed.

AMS PROCESS REQUIREMENTS FLOW CHART



AMS MICROBIAL REQUIREMENTS FOR GROUND BEEF

Microbial Test	Upper Specification Limits	Critical Limits	CI or C_{pu} Value
Standard Plate Count	100,000/gram	500,000/gram	$C_{pu} \geq 1$
Total <i>Coliforms</i>	500/gram	2,500/gram	$C_{pu} \geq 1$
<i>E.coli</i>	100/gram	1,000/gram	$C_{pu} \geq 1$
Coagulase Positive <i>Staphylococci</i>	500/gram	2,500/gram	$C_{pu} \geq 1$
<i>Salmonella</i>		Positive Results/25 grams	$CI \leq 0.05$
<i>E. coli</i> O157:H7		Positive Results/325 grams	$CI \leq 0.05$

APPENDIX D

Glossary of Terms

Statistical Process Control (SPC) – SPC is the primary analysis tool of quality improvement. The objective of any quality improvement strategy is to identify and reduce the amount of variation. SPC analyzes the variation in a process and is the applied science that will assist suppliers to collect, organize and interpret microbial and fat test results on processing of ground beef destined for USDA.

SPC provides tools to help measure, identify, and eliminate variation from customer requirements.

Tools for Statistical Process Control	
Flow Charts	Scatter Diagrams
Pareto Diagrams	Run Charts
Cause and Effect Diagrams	Control Charts
Histograms	Capability Assessment

Flow Charts – Flow charts depict all of the steps of a process. Standard symbols are used to identify the start, finish, processing steps and decision steps. It can be used to simplify a complex process so that it can be analyzed (Figure 1).

Process – For the purpose of this specification, a single process involves the input of a raw material on a production line with a value added activity resulting in a output that can be further processed or meet a customer's need. A complex process involves output being another processes input. The production of ground beef is a complex process.

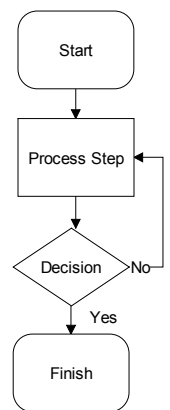
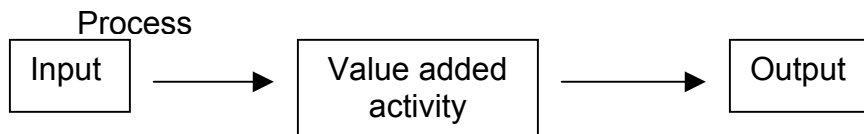
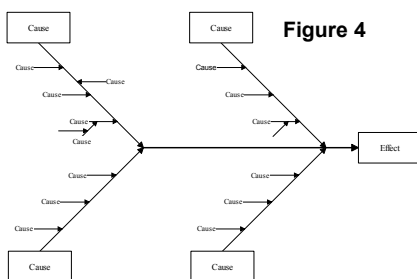
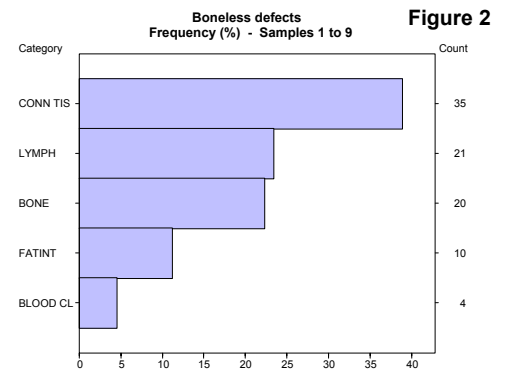


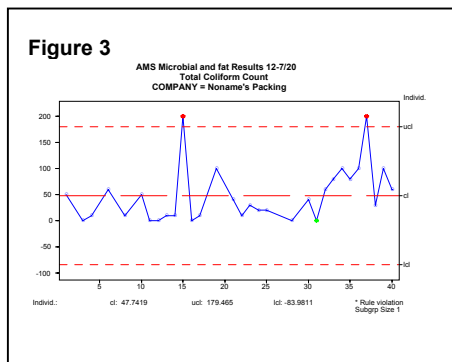
Figure 1

Pareto Diagrams – The Pareto diagram ranks the importance of different non-conformities. Typically, non-conformities are measured against frequency of occurrence. The Pareto analysis is helpful in identifying and justifying which problems will need to be solved first (see Figure 2)



Cause and Effect Diagrams – A cause and effect analysis is used to identify the cause or source of non-conformities. It categorizes the source as derived from impact on a process presented by Human, Machinery, Material, Methods, Environment, and Measurement (Test). The Cause and Effect

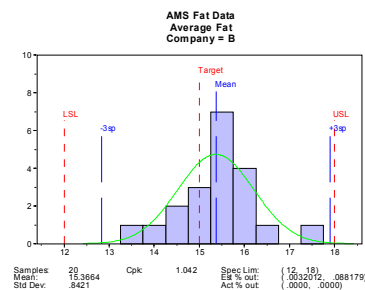
Diagram will assist in evaluating a process and assigning the appropriate control point (see Figure 3)



Control Charts – A control chart is a run chart with statistically derived upper and lower control limits (ucl and lcl). The control chart demonstrates if a process is in statistical control. When properly designed, control charts provide an early warning of problems allowing for adjustments to be made before production of non-conforming products. We recommend microbial test results be plotted on control charts for individual measurements with moving range and fat test results be plotted on control charts featuring average and range of the fat test results (See Figure 4).

Upper and lower control limits (ucl and lcl) – Control limits are statistical calculations of the distribution of test results. Upper and lower control limits represent +/- 3 standard deviations of the process results. Data plotted outside the limits represent special causes of variation. A process may be considered “out of statistical control” when results are outside these limits. Upper and lower control limits are not to be confused with specification limits. A supplier wishing to be an eligible participant in the Ground Beef Program shall have a process that is capable of producing within the specification limits.

Upper and lower specification limits (USL and LSL) – Normally, the customer sets the specification limits. The objective of the Ground Beef Purchase Program is to procure from ground beef processors that are statistically capable of meeting the upper specification limits specified within the TRS-GB. The specification limits reflect customer needs (See Figure 5).



Histograms – The histogram shows a pictorial representation of the frequency of distribution of microbial test results over time. Sometimes referred to as process capability charts, histograms compare the distribution of the test results with AMS specification requirements. Use histograms along with control charts to better understand process capability (See Figure 5).

Figure 5

C_{pk} – Process Capability Value (C_{pk}) is a capability analysis index used to determine if a process can meet specification limits. A C_{pk} value of 1 indicates that the process is producing at least 99.73% within the specification limit. C_{pk} values of 1 for many organizations have become the minimum requirement. However, the larger the C_{pk} values the better. C_{pk} differs from other process capability analyses since it considers the process average along with the distribution of test results. Since there is no lower specification limit for USDA microbial requirements, the calculation for C_{pk} will not involve relating the process average with a lower specification limit.

C_{pu} - Process Capability Value (C_{pu}) is the same as C_{pk} except that there is no lower specification limit. The process performance index is correctly known as a Centered Process Capability Upper Specification Limit only (C_{pu}) (See Figure 5).

Excellent Condition - All product must be in excellent condition; e.g., exposed lean and fat surfaces shall be of a color and bloom normally associated with the class, grade, and cut of meat, and typical of meat which has been properly stored and handled. Cut surfaces and naturally exposed lean surfaces shall show no more than slight darkening or discoloration due to dehydration, aging, and/or microbial activity. The fat shall show no more than very slight discoloration due to oxidation or microbial activity. No odors foreign to fresh meat shall be present. Changes in color and odors characteristically associated with vacuum packaged meat in excellent condition shall be acceptable. Also, product shall show no evidence of mishandling. Beef must be maintained in excellent condition through processing, storage, and transit.